

moving the outer shaft relative to the inner shaft.

17. (currently amended) The method of Claim 8 16 further including the step of:

releasably connecting the lancet to the outer shaft.

18. (previously presented) The method of Claim 8 further including the step of:

releasably connecting an end cap to the housing.

19. (currently amended) The method of Claim 8 wherein the member is selectively held

in the armed position or released from the armed position by a switch, such switch is selectively engaging or disengaging a member, the member is being held in the armed position and the lancet is in the withdrawn position when the switch engages the member and the member and lancet being free to move from the armed and withdrawn positions when the switch is disengaged from the member.

20. (cancelled)

21. (currently amended) The method of Claim 8 wherein the step of position either the

member or the permanent magnetic element to an armed position wherein the magnetic forces from the permanent magnetic element affecting the member involves moving an arming member which mechanically moves ~~the~~ a collar from the steady state position to the armed position.

22. (previously presented) The method of Claim 21 further including the step of:

holding the arming member to the housing by at least one spring.

REMARKS

Summary of the Office Action and Applicants' Reply

Claims 1-7 have been rejected under 35 U.S.C. 102(a) as being anticipated by Freeman, U.S. 2003/0083686 (hereinafter referred to as "Freeman"). Claims 8-15 and 18-19 have been

rejected as reading onto Freeman's embodiment in figures 20-22. Freeman claims a controllable lancet driver comprising a drive force generator, a controller, and a lancet. The drive force generator is an electric field of coils or solenoids that drive the lancet using electromagnetic force. The advancement and retraction of the lancet may be controlled by a feedback loop monitoring the position and velocity of the lancet embodiments of the lancet driver that can be configured to follow a predetermined tissue lancing profile. The driver uses a magnetic member which is an electromagnetic force generating member. The magnetic force is controllable and a permanent magnet is used only for zeroing the position of the magnetic member when the tissue penetration device is inactive.

Freeman includes a solenoid that creates an electromagnetic force, while Applicant's device uses only a permanent magnet to drive the lancet. When comparing the two devices, Applicant's device does not require an electric current that Freeman uses.

With respect to the Examiner's rejections of Claims 1-7, Applicant respectfully requests that the Examiner consider that the Figure 5 of Freeman depicts an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the lancet using direct current. (Freeman, paragraph 0137). Direct current is alternated through the coils to advance and retract the lancet. *Id.* Applicant's device is substantially different because it uses only a permanent magnet; there is no need for a power supply. While the end result of driving the lancet into tissue may result in both devices, the ways of doing this are substantially different from each other. As such Applicant's Claims 1-7 are not anticipated by Freeman are in fact a different invention. Applicant has amended Claims 1-7 to clarify the presence of a permanent magnetic element.

With respect to Applicant's claims 8-15 and 18-19, Applicant argues again that the claims are not reading onto Freeman's embodiments, especially those seen in Freeman Figures 20-22. Freeman coils 214-217 are used to carry electrical current. (Freeman, paragraph 0137) The Freeman permanent bar magnet 219 is simply used to hold the device in a rest or zero position without the consumption of electrical energy. (Freeman, paragraph 0175). Freeman paragraph 0174 discusses that it may be advantageous to replace coils with magnets to provide a zeroing (rest) position for the magnetic member. Applicant's device uses permanent magnets throughout and does not require an electrical energy supply. Magnets are not just used to hold a rest position. Permanent magnets drive Applicant's device. In Freeman, the coils 214-217 are activated by driving an electrical energy supply through them to create a current.

With respect to Claim 9, Applicant argues that Freeman utilizes a permanent bar magnet 219 to hold the device in a rest position to conserve energy. Freeman's permanent bar magnet 219 holds member 202 in place to achieve that goal of conservation of energy. Applicant's device has no such electrical energy supply to conserve. The permanent magnet in Applicant's device is either activated or not activated; it either is driving the lancet or it is not. There is no need to control the device due to electrical power supplies such as in Freeman.

Claim 10 should be allowable as it is dependent on Claim 8, which has been argued above over the Freeman rejection.

With regard to Claim 11, Applicants' magnetic element and member are not the same as the coils 214-217 that conduct electrical current where the member 202 passes through. The member 202 only passes through when the coils are activated with an electrical current. Applicant's movement is quite different from this movement as outlined above in discussing of powering movement with an electrical energy supply.

With regard to claim 12, this too relates to the differences in the way the lancet moves in Freeman and in Applicant's device. Applicant's lancet must be allowed to move to pierce the tissue and it must communicate with the member to do this. This is done through permanent magnets.

With respect to Claim 13, Applicant does not "draw current". Applicant's device simply relies on magnetic forces to move rather than electromagnetic forces. Freeman's discussion of replacing the coils 214-217 with magnets is simply to increase the electromagnetic forces within the invention rather than the permanent magnetic forces, such as in Applicant's invention. It is important to note that Freeman's magnetic field is an electromagnetic field whereas Applicant's magnetic field is not.

With respect to Claim 14, the magnetic element 219 is used to hold the device in a rest position to conserve energy. Freeman's permanent bar magnet 219 holds member 202 in place to achieve that goal of conservation of energy. Freeman paragraph 0175.

With respect to Claim 15, a similar argument as stated above in respect to Claim 13. Freeman's discussion relates to electromagnetic forces rather than permanent magnetic forces.

With respect to Claim 18, the end cap and the disposable sampling module 410 of the Freeman device are different. Freeman describes the sampling module 410 as being capable of transporting the blood sample to the analytical region. Freeman, paragraph 0240. Applicant's end cap simply protects the lancet and its respective tip and point. This is quite a different function.

With respect to Claim 19, Applicant's switch is not similar to Freeman switch. Freeman's switch opens an electric circuit when a driver is activated causing the tissue to be lanced. Applicant's switch simply frees the magnet to move and pierce the tissue.

Claim Rejections

Claims 17 and 21 have been amended to overcome the rejection under 35 U.S.C. 112.

Claim Objections

Claim 20 has been cancelled rendering the objection regarding Claim 20 moot.

Allowable Subject Matter

Claim 16 is dependent on Claim 8. Applicant is choosing not to amend claim 16 at this time pending the Examiner's review of the remarks as they relate to Claim 8.

Claim 20 has been cancelled.

Claim 22 has been amended.

Authorization


The Director is hereby authorized to charge any additional fees which may be required for this Reply, or credit any overpayment, to Deposit Account No. 50-3791.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Director is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3791.

Respectfully submitted,

Date: _____

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